Medica Central Coverage Policy

Policy Name:	**Radiofrequency Spectroscopy for Intra-Operative Assessment of Surgical Margins in Breast Cancer (e.g., MarginProbe) MP9792**
Effective Date:	**January 01. 2025**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Radiofrequency Spectroscopy for Intra-Operative Assessment of Surgical Margins in Breast Cancer (e.g., MarginProbe) is considered investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description

According to the American Society of Clinical Oncology (ASCO), surgical excision of cancerous tissue is a mainstay of breast cancer treatment. Breast-conserving lumpectomy (also referred to as partial mastectomy, quadrantectomy, or a segmental mastectomy) is performed for some patients with early stage localized breast cancer who may not require a full mastectomy. It entails removing the tumor and some surrounding healthy tissue to ensure that all of the cancer is removed. Removal of surrounding healthy tissue, referred to as the margins, is intended to ensure that all cancerous tissue is removed with the intent of minimizing the chance of local recurrence. Positive surgical resection margins following breast conservation surgery (BCS) are a strong risk factor for local recurrence. In addition, a positive surgical margin may require additional surgery, with increased potential for morbidity and mortality, compromised quality of life.

MarginProbe is intended to be used as an adjunct diagnostic tool during breast cancer surgery to inform whether surgical margins are "clear," or if further tissue removal is warranted. It is thereby

meant to increase the likelihood that all cancer is removed during lumpectomy and to reduce the likelihood that repeat surgery will be needed.

The MarginProbe system includes a freestanding portable console unit with a user interface and a disposable, sterile probe. In using MarginProbe, a surgeon takes 5 to 8 measurements per margin surface of a lumpectomy specimen by touching the disposable probe to the specimen surface. Via the probe, readings are displayed on the MarginProbe system console as either positive or negative. Each measurement takes approximately 1 second. A classification algorithm compares the specimen with known tissues in a database of cancerous and noncancerous breast tissues, generating visible and audible output that categorizes the specimen surface as positive or negative for the presence of cancer cells.

FDA Approval

MarginProbe® received FDA premarket approval (PMA) approval in January 2013. The Dune MarginProbe®™ System is an adjunctive diagnostic tool for identification of cancerous tissue at the margins (≤1 mm) of the main ex-vivo lumpectomy specimen after primary excision. It is indicated for intraoperative use in conjunction with standard methods (e.g., intraoperative imaging and palpation) for patients undergoing lumpectomy for previously diagnosed breast cancer. In 2016, MarginProbe® received FDA premarket approval on modifications which made the device compliant with the European Union's Restriction of Hazardous Substances requirements. Additional modifications included an updated results display screen and improved CPU.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

Use the current applicable CPT/HCPCS code(s).

Original Effective Date: 01/01/2025

Re-Review Date(s):

Administrative Update: